FEB 2 8 2014

K133671

stryker

Endoscopy

510(k) Summary of Safety and Effectiveness

Proprietary Name:	ICONIX All Suture Anchor System
Common Name:	Fastener, Fixation, Nondegradable, Soft Tissue
Classification Name and Reference:	Smooth or threaded metallic bone fixation fastener 21 CFR §888.3040
Proposed Regulatory Class:	Class II
Product Codes:	MBI: Fastener, Fixation, Nondegradable, Soft Tissue
Device Owner:	Stryker Endoscopy 5900 Optical Court San Jose, CA 95138
For Information Contact:	Kelly Kucharczyk Regulatory Affairs Specialist Howmedica Osteonics Corp. 3201 E. 3rd Ave Denver, CO 80210 Phone: (303) 336-7285; Fax (303) 370-5775 Email: kelly.kucharczyk@stryker.com
Legally Marketed Devices to Which Substantial Equivalence Is Claimed:	K120509 – Stryker All Suture Anchors K110545 – Smith & Nephew Next Generation Fully Threaded PEEK Suture Anchor (marketed as the Healicoil PK Suture Anchor)
Date Prepared:	November 26, 2013

Description

This Traditional 510(k) is being supplied to the U.S. FDA to expand the indications of the Stryker All Suture Anchors (K120509) (currently marketed as the ICONIX All Suture Anchor System) to include Gluteal Tendon Repair of the Hip. The ICONIX All Suture Anchors are soft-tissue fixation devices with a push-in design, provided preloaded on a disposable inserter. They are composed of a sheath structure that contains one or more working sutures. As the anchor is deployed, the sheath bunches and fixates in bone. There have been no design modifications to the ICONIX All Suture Anchors since the original clearance (K120509).

Intended Use

The ICONIX All Suture Anchor System is intended to be used for soft-tissue to bone fixation in the foot, ankle, knee, hip, hand, wrist, elbow and shoulder. Specific Indications are listed below.

Indications

Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction

Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Repair

Hand/Wrist: Scaphulolunate Ligament Reconstruction, Carpal Ligament Reconstruction, Repair/Reconstruction of Collateral Ligaments, Repair of Flexor and Extensor Tendons at the PIP, DIP and MCP Joints for all Digits, Digital Tendon Repair

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Metatarsal Ligament Repair, Hallux Valgus Reconstruction, Digital Tendon Transfers, Mid-foot Reconstruction

Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis.

Hip: Capsular Repair, Acetabular Labral Repair, Gluteal Tendon Repair

The ICONIX All Suture Anchors are intended for single use only.

Summary of Technologies

The ICONIX All Suture Anchors are substantially equivalent in design, materials of construct, performance attributes, and operational principles to its currently marketed predicate devices, the Stryker All Suture Anchors (currently marketed as the ICONIX All Suture Anchor System) and the Smith and Nephew Next Generation Fully Threaded PEEK Suture Anchor (currently marketed as the Healicoil PK Suture Anchor).

Non-Clinical Testing

In order to support the additional indication, non-clinical comparative bench testing was performed to verify the fixation strength of the ICONIX All Suture Anchors. Cyclic testing followed by ultimate tensile strength was evaluated in order to support the efficacy of the ICONIX All Suture Anchors as compared to the predicate devices identified within this premarket notification. The results of this evaluation indicate that the ICONIX All Suture Anchors provide statistically equivalent fixation strength to the predicate devices, and will be functional within the intended use.

Clinical Testing

Clinical testing was not required for this submission.

Conclusion

Based on the information discussed above, the ICONIX All Suture Anchors are as safe, as effective, and perform as well or better to the predicate devices listed within this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

February 28, 2014

Stryker Endoscopy
Ms. Kelly Kucharczyk
Regulatory Affairs Specialist
5900 Optical Court
San Jose, California 95138

Re: K133671
Trade/Device Name: ICONIX All Suture Anchor System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: November 26, 2013
Received: December 4, 2013

Dear Ms. Kucharczyk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Vincent J. Devlin -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K133671

Device Name: ICONIX All Suture Anchor System

Elbow: Biceps Tendon Re-attachment, Ulnar or Radial Collateral Ligament Reconstruction

Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Repair

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Hip: Capsular Repair, Acetabular Labral Repair, Gluteal Tendon Repair

The ICONIX All Suture Anchors are intended for single use only.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Casey L. Hanley, Ph.D.

Division of Orthopedic Devices